

## Remarks

### Support for the amendments

The claim amendments are fully supported by the previously pending claims, and thus do not constitute new matter.

### Claim Rejections under 35 USC 112 first paragraph: Written Description

The patent office rejected claims 49-54, 57-62, and 65-66 under 35 USC 112 first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the invention at the time the application was filed. The applicants traverse this rejection.

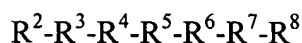
"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.* 107 F.3d 1565, 1572 (Fed. Cir. 1997) and MPEP 2163.02. As specifically stated in this same MPEP section, "*Possession may be shown in a variety of ways*, including description of an actual reduction to practice, *or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show the invention was complete*, or by *describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.*" Thus, the MPEP clearly states that an actual reduction to practice is not required to satisfy the written description requirement.

In contrast, the patent office has, in the present case, stated that the asserted failure to satisfy the written description requirement is based on the lack of data in the specification for the use of SEQ ID NO:18 to treat or prevent bone disorders that result in weakened bones. (See page 4 first paragraph, particularly the last line.) As noted by the applicants in the preliminary amendment in which the presently pending claims were introduced, the specification provides support for the presently pending claims at, for example, page 8 lines 11-19; page 8 line 22 to page 9 line 3; and page 34 lines 6-12. Specifically, page 8 line 22 to page 9 line 3 states as follows:

"The present invention fulfills the need for methods to enhance bone repair in a mammal suffering from bone fractures, defects, and disorders which result in weakened bones such as osteoporosis, osteoarthritis, Paget's disease, osteomalacia, osteomalacia, periodontal disease, bone loss resulting from multiple myeloma and other forms of cancer, bone loss resulting from side effects of other medical treatment (such as steroids), and age-related loss of bone mass."

Furthermore, on page 16 line 11 to page 17 line 6, the specification states:

"Another class of compounds of particular interest in accordance with the present invention are those of the general formula II



in which  $R^2$  is selected from the group consisting of H, Arg, Lys, Ala, Orn, Citron, Ser(Ac), Sar, D-Arg and D-Lys;

$R^3$  is selected from the group consisting of Val, Ala, Leu, norLeu, Ile, Gly, Pro, Aib, Acpc and Tyr;

$R^4$  is selected from the group consisting of Tyr, Tyr(PO<sub>3</sub>)<sub>2</sub>, Thr, Ser, homoSer, Ala, and azaTyr;

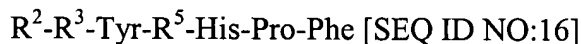
$R^5$  is selected from the group consisting of Ile, Ala, Leu, norLeu, Val and Gly;

$R^6$  is His, Arg or 6-NH<sub>2</sub>-Phe;

$R^7$  is Pro or Ala; and

$R^8$  is selected from the group consisting of Phe, Phe(Br), Ile and Tyr.

A particularly preferred subclass of the compounds of general formula II has the formula



wherein  $R^2$ ,  $R^3$  and  $R^5$  are as previously defined. Particularly preferred is angiotensin III of the formula Arg-Val-Tyr-Ile-His-Pro-Phe [SEQ ID NO:2]. Other preferred compounds include peptides having the structures Arg-Val-Tyr-Gly-His-Pro-Phe [SEQ ID NO:17] and Arg-Val-Tyr-Ala-His-Pro-Phe [SEQ ID NO:18]. The fragment AII(4-8) was ineffective in repeated tests; this is believed to be due to the exposed tyrosine on the N-terminus."

Thus, one of skill in the art would clearly be aware that the specification discloses the use of active agents, including SEQ ID NO:18, for treating or preventing bone

disorders that result in weakened bones. As stated in MPEP 2163.02, "*Possession may be shown in a variety of ways, including by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show the invention was complete...*" Thus, it is clear that the applicants were in possession of the claimed invention, as per MPEP 2163.02, and thus the written description requirement of 35 USC 112 first paragraph has been met.

Based on the above, the applicants respectfully request reconsideration and withdrawal of the written description rejection.

### **Claim Rejections under 35 USC 112 first paragraph: Enablement**

The patent office rejected claims 49-54, 57-62, and 65-66 under 35 USC 112 first paragraph as containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to make and/or use the invention. Specifically, the patent office asserts that the specification does not enable the use of SEQ ID 18 according to the claimed methods, nor for using any peptides for preventing bone disorders that result in weakened bones. The applicants traverse this rejection.

The patent office has admitted that the specification enables the scope of the claim with respect to SEQ ID NOs 1, 4, and 45 (see page 7, first paragraph). The patent office further indicated that the specification is enabling for methods of treating bone disorders that result in weakened bones. (See page 7, second full paragraph.) The applicants are herewith submitting a declaration from Dr. Kathleen Rodgers which provides confirmatory data that shows, using the techniques disclosed in the specification (specifically, Figure 2), the efficacy of 10 more peptides falling within the genus on treating bone disorders that result in weakened bones.

Specifically, the confirmatory data demonstrate that the peptides of the invention accelerate the formation of new bone tissue.

The peptides tested were the following:

<b>Peptide</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
Lys1AIII	--	K	V	Y	I	H	P	F
HomoSer3 AIII	--	R	V	HomoSer	I	H	P	F
NorLeu3 AII	D	R	NorLeu	Y	I	H	P	F
Ala4 AIII	--	R	V	Y	A	H	P	F
AIII	--	R	V	Y	I	H	P	F

Lys2 AII	D	K	V	Y	I	H	P	F
HomoSer4 AII	D	R	V	HomoSer	I	H	P	F
NorLeu2 AIII	--	R	NorLeu	Y	I	H	P	F
Leu4 AIII	--	R	V	Y	L	H	P	F

These peptides are in addition to those demonstrated in the application:

AII(1-7)	DRVYIHP--	SEQ ID NO:4
AII	DRVYIHPF	SEQ ID NO. 1
9GD: NorLeu3-AII(1-7)	DR(nor)YIHP--	SEQ ID NO:45

Thus, using the techniques disclosed in the specification, the applicants have confirmed that a large number of peptides falling under the claimed genus can be used to carry of the methods of the invention. Therefore, it is clear that the specification enables those of skill in the art to make and use the invention as claimed.

Nevertheless, in order to accelerate prosecution of the pending application, the applicants have amended the claims, without prejudice to their re-filing in a continuing application, to obviate the enablement rejection. Thus, the applicants respectfully request reconsideration and withdrawal of the rejection.

#### **Claim Rejections under 35 USC 112 second paragraph**

(a) Claims 49-54, 57-62, and 65-66 were rejected under 35 USC 112 second paragraph as indefinite, based on the assertion that the recitation of the genus rendered the claim indefinite to one of skill in the art. The applicants traverse this rejection, as those of skill in the art will clearly understand the scope of the invention. The amended claim recites a genus that is very well defined and clearly points out the subject matter which the applicants regard as the invention. Thus, the applicants respectfully request reconsideration and withdrawal of the rejection.

(b) Claim 49 was rejected under 35 USC 112 second paragraph as indefinite, based on the assertion that it was unclear what bone disorders result in weakened bones, and the lack of the modifier "the" in the second recitation of "bone disorder." The Applicants traverse this rejection, but have nonetheless amended claim 49 to recite the bone disorders, thus obviating the rejection.

#### **Double patenting**



(a) The patent office rejected claims 49-54, 57-62, and 65-66 for obviousness-type double patenting over claims 1-2 of U.S. Patent No. 6,248,587. The Applicants traverse this rejection but are nonetheless herewith filing a terminal disclaimer, and thus respectfully request withdrawal of the rejection.

(b) The patent office rejected claims 49-54, 57-62, and 65-66 for obviousness-type double patenting over claims 1-2 of U.S. Patent No. 6,498,138. The Applicants traverse this rejection but are nonetheless herewith filing a terminal disclaimer, and thus respectfully request withdrawal of the rejection.

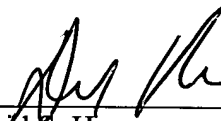
In light of the above amendments and arguments, the applicants believe that the application is now in condition for allowance. If there are any questions about this response, the Examiner is respectfully requested to call the below-signed attorney for the Applicants at (312) 913-2106.

Respectfully submitted,

**McDonnell Boehnen Hulbert & Berghoff**

Date: 2/10/04

By:

  
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David S. Harper  
Reg. No. 42,636